STATUTORY INSTRUMENTS

2013 No. 349

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

PART 7

Areas that are controlled localities or reserved locations, and new pharmacies within them

Determination that an area is a controlled locality

36.—(1) Any area that was, or was part of, a controlled locality for the purposes of the 2012 Regulations immediately before these Regulations come into force continues to be, or to be part of, a controlled locality for the purposes of these Regulations (unless or until it is determined that the area is no longer, or no longer part of, a controlled locality).

(2) Subject to paragraph (3), the NHSCB may at any time consider and determine whether or not any locality, because it is rural in character, is to be, or to be part of, a controlled locality.

(3) Where the question of whether or not an area is to be, or to be part of, a controlled locality has been determined by the NHSCB, a Primary Care Trust or on appeal (whether under these Regulations, the 2012 Regulations or the 2005 Regulations), that question must not be considered again in relation to that area—

(a) for 5 years, beginning with the date of the determination of the NHSCB or the Primary Care Trust, or if that determination was appealed, the date of the decision on appeal;

(b) unless the NHSCB is satisfied (within that 5 years) that there has been a substantial change in circumstances in relation to that area since the question was last determined.

Process for determining controlled localities: preliminary matters

37.—(1) A Local Medical Committee or Local Pharmaceutical Committee may apply in writing to the NHSCB for it to determine whether or not an area specified in the application (which must be all or part of the Committee's area) is to be, or is to be part of, a controlled locality.

(2) Before considering the application, the NHSCB must consider whether or not the application raises a question that it cannot consider by virtue of regulation 36(3).

(3) If the NHSCB decides that the application does raise a question that it cannot consider by virtue of regulation 36(3), it must take no further action in relation to that application other than informing the Committee making the application of that decision and its right of appeal against that decision under regulation 45(1)(b).

Process for determining controlled localities: local notification and deferment of routine applications

38.—(1) If the NHSCB is considering making a determination that an area (A1) is or is not to be, or is or is not to be part of, a controlled locality (whether or not of its own motion), before making the proposed determination, it must give notice of the proposed determination to—

(a) any Local Pharmaceutical Committee whose area includes all or part of A1;

(b) any Local Medical Committee whose area includes all or part of A1;

(c) any person on a pharmaceutical list or dispensing doctors list who, in the opinion of the NHSCB, may be affected by the determination;

(d) any LPS chemist who, in the opinion of the NHSCB, may be affected by the determination;

(e) any provider of primary medical services who, in the opinion of the NHSCB, may be affected by the determination;

(f) where it is considering making a determination as a consequence of a routine application, the person making that application; and

(g) any HWB whose area includes all or part of A1.

(2) The NHSCB may also give notice of the proposed determination to such other persons as it considers appropriate to do so.

(3) A notice under paragraph (1) or (2) must inform the person notified—

(a) that they may make representations (or in the case of a Committee being notified that applied for the determination, any further representations) in writing within 30 days beginning on the day on which the notification was sent to them;

(b) of the date by which the NHSCB expects to make its determination, which must be no later than 6 months after the day on which the NHSCB first gives notice to any person in respect of the proposed determination under paragraph (1) or (2).

(4) Once the NHSCB has issued notice under paragraph (1), it must defer consideration of any routine application where the applicant is seeking the listing of pharmacy premises and the outcome of the application could (if the application is deferred) be affected as a result of the proposed determination, until—

(a) it has determined whether the area in question is or is not to be, or is or is not to be part of, a controlled locality; and

(b) the proceedings relating to that determination have reached their final outcome.

Process of determining controlled localities: formulation of the NHSCB's decision

39.—(1) When it is determining whether or not an area is or is part of a controlled locality, the NHSCB must have regard to whether the provision of—

(a) primary medical services by a provider of primary medical services;

(b) pharmaceutical services by a person on a pharmaceutical list; or

(c) local pharmaceutical services by a provider of such services,

is likely to be adversely affected by the consequences of the determination.

(2) Once it has determined whether or not an area is or is part of a controlled locality, the NHSCB must—

(a) if it determines that the area is to become or become part of a controlled locality, or is to cease to be part of a controlled locality—

(i) delineate precisely the boundary of the resulting controlled locality on a map,

(ii) publish that map, and

(iii) make that map available as soon as is practicable to any HWB that has all or part of that controlled locality in its area;

(b) give notice of the determination to the persons mentioned in paragraph (3) informing them of—

(i) its determination and the reasons for it,

(ii) their right of appeal, if the person has a right of appeal under regulation 45(1)(a)(i), and

(iii) their right of appeal under regulation 45(1)(a)(ii), in the case of a person notified who is a Local Pharmaceutical Committee, a Local Medical Committee, a provider of primary medical services, an LPS chemist or a person on a pharmaceutical or dispensing doctors list.

(3) The persons mentioned in this paragraph are—

(a) if the determination resulted from an application from a Local Pharmaceutical Committee or Local Medical Committee pursuant to regulation 37(1), that Committee;

(b) if a routine application was deferred pursuant to regulation 38(4) until the proceedings relating to the determination reached their final outcome, the person making that application; and

(c) the persons notified in accordance with regulation 38(1) and (2) in relation to the proposal to make the determination.

(4) A HWB to which a map is made available under paragraph (2)(a)(iii) must—

(a) publish that map alongside its pharmaceutical needs assessment map (once it has one); or

(b) include the boundary of the controlled locality (in so far as it is in, or part of the boundary of, the HWB's area) in its pharmaceutical needs assessment map (once it has one).

Applications for new pharmacy premises in controlled localities: refusals because of preliminary matters

40.—(1) This paragraph applies to all routine applications—

(a) for inclusion in a pharmaceutical list as an NHS pharmacist; or

(b) from an NHS pharmacist included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, additional pharmacy premises from which to provide pharmaceutical services,

where the applicant is seeking the listing of pharmacy premises which are in a controlled locality.

(2) If the NHSCB receives an application (A1) to which paragraph (1) applies, it must refuse A1 (without needing to make any notification of that application under Part 3 of Schedule 2), where the applicant is seeking the listing of premises at a location which is—

(a) in an area in relation to which outline consent has been granted under these Regulations, the 2012 Regulations or under the 2005 Regulations within the 5 year period—

(i) starting on the date on which the proceedings relating to the grant of outline consent reached their final outcome, and

(ii) ending on the date on which A1 is made; or

(b) within 1.6 kilometres of the location of proposed pharmacy premises (other than proposed distance selling premises), in respect of which—

(i) a routine application under these Regulations or the 2012 Regulations, or

(ii) an application to which regulation 22(1) or (3) of the 2005 Regulations (relevant procedures for applications) applied,

was refused within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made,

unless the NHSCB is satisfied that since the date on which the 5 year period started, there has been a substantial and relevant change of circumstances affecting the controlled locality.

(3) For the purposes of paragraphs (1) and (2), if no particular premises are proposed for listing in A1, the applicant is to be treated as seeking the listing of pharmacy premises at the location which is the best estimate that the NHSCB is able to make of where the proposed listed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

[F1(4) Paragraph (2)(b) does not apply where the NHSCB is satisfied that there are reasonable grounds for believing the person making the refused application was motivated (wholly or partly) by a desire for that application to be refused.

(5) The refusal of an application pursuant to paragraph (2)(b), or regulation 40(2)(b) of the 2012 Regulations (applications for new pharmacy premises in controlled localities: refusals because of preliminary matters), is to be ignored for the purposes of the calculation of a 5 year period pursuant to paragraph (2)(b).**]**

F1 Reg. 40(4)(5) inserted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, **14**

Applications for new pharmacy premises in controlled localities: reserved locations

41.—(1) This paragraph applies to any routine application—

(a) for inclusion in a pharmaceutical list as an NHS pharmacist; or

(b) from an NHS pharmacist included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, additional pharmacy premises from which to provide pharmaceutical services,

where the applicant is seeking the listing of pharmacy premises which are in a controlled locality and the NHSCB is required to notify the application under Part 3 of Schedule 2.

(2) If paragraph (1) applies to an application (referred to in this regulation and regulation 42 as "A1"), subject to paragraph (5), the NHSCB must determine whether or not the "relevant location", that is—

(a) the location of the premises for which the applicant is seeking the listing; or

(b) if no particular premises are proposed for listing in A1, the location which is the best estimate that the NHSCB is able to make of where the proposed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2,

is, on basis of the circumstances that pertained on the day on which A1 was received by the NHSCB, in a reserved location.

(3) Subject to regulation 43(2), the area within a 1.6 kilometre radius of a relevant location is a "reserved location" if—

(a) the number of individuals residing in that area who are on a patient list (which may be an aggregate number of patients on more than one patient list) is less than 2,750; and

(b) the NHSCB is not satisfied that if pharmaceutical services were provided at the relevant location, the use of those services would be similar to, or greater than, the use that might be expected if the number of individuals residing in that area who are on a patient list were 2,750 or more.

(4) Before making a determination under paragraph (2) (referred to in this regulation and regulation 42 as "D1"), the NHSCB must—

(a) notify the persons notified under Part 3 of Schedule 2 about A1 that the NHSCB is required to make D1 (and it may make this notification at the same time as it notifies those persons about A1); and

(b) invite them, within a specified period of not less than 30 days, to make representations to the NHSCB with regard to D1 (and the period specified must end no earlier than the date by which the person notified needs to make any representations that they have with regard to A1).

(5) The NHSCB must not make a determination under paragraph (2) in respect of A1 in circumstances where an earlier application which was in respect of the relevant premises and to which paragraph (1), regulation 44(1) of the 2012 Regulations (prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location) or regulation 18ZA of the 2005 Regulations [M1] (refusal: premises which are in a controlled locality but not a reserved location) applied was refused—

(a) for the reasons relating to prejudice in—

(i) regulation 44(3),

(ii) regulation 44(3) of the 2012 Regulations, or

(iii) regulation 18ZA(2) of the 2005 Regulations; and

(b) within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made,

unless the NHSCB is satisfied that since the date on which the 5 year period started, there has been a substantial and relevant change of circumstances affecting the controlled locality.

(6) For the purposes of paragraph (5), the "relevant premises" are—

(a) the premises which are proposed for listing; or

(b) if no particular premises are proposed for listing in A1, premises at the location which is the best estimate that the NHSCB is able to make of where the proposed listed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

Marginal Citations

M1 Prior to its revocation, regulation 18ZA was inserted by S.I. 2005/1501.

Second and subsequent determinations of reserved location status

42.—(1) Where the NHSCB has made D1, or a reserved location determination has been made in accordance with the 2012 Regulations or the 2005 Regulations, and the person in relation to whose proposed listing of premises that determination was made (or that person's successor as the owner of the relevant pharmacy business) requests a further determination (referred to in this regulation as "D2"), the NHSCB may determine (subject to paragraph (3) and regulation 43(2))—

(a) whether or not a location that has become the relevant location for the purposes of a listing application is in a reserved location, on the basis of the circumstances that pertained on the day on which the request for D2 was received by the NHSCB, in circumstances where the relevant location in relation to which the earlier determination was made has changed because—

(i) no particular premises were proposed for listing in the application, but

(ii) particular premises have since been identified; or

(b) that, on the basis of the circumstances that pertained on the day on which the request for D2 was received by the NHSCB, there is no longer—

(i) a reserved location, or

(ii) in the case of a determination of a reserved location that has not yet taken effect, a determination of a reserved location,

with regard to the premises proposed for listing (which may have become pharmacy premises) because the relevant location no longer meets (or does not meet) the criteria for being a reserved location in regulation 41(3).

(2) Before making D2, the NHSCB must—

(a) notify the persons that it would notify under Part 3 of Schedule 2, if the request for a determination were an application seeking the listing of pharmacy premises at the relevant location, that the NHSCB is required to make a determination under paragraph (1); and

(b) invite them, within a specified period of up to 3 months but not less than 30 days, to make representations to the NHSCB with regard to that determination.

(3) The NHSCB must only determine under paragraph (1) that the area, or any part of an area, that is within a 1.6 kilometre radius of a relevant location is no longer to be classed as a reserved location if it is satisfied that the change in classification of that area, or part of an area, will not prejudice the proper provision of relevant NHS services in the area of—

(a) the relevant HWB; or

(b) a neighbouring HWB of the relevant HWB.

(4) Where the NHSCB makes D2—

(a) D1 lapses as soon as D2 is made; and

(b) the NHSCB may (in accordance with regulation 50) postpone the termination of the arrangements that it has with the provider of primary medical services or dispensing doctor that would otherwise take place as a consequence of D2.

(5) Where—

(a) the NHSCB has made D2; and

(b) the person who sought the determination, or that person's successor as the person carrying on a pharmacy business at the relevant location, believes that the reserved location no longer meets the criteria for being a reserved location in regulation 41(3),

that person may request a further determination, under paragraph (1)(b), and if that person does, paragraphs (1) to (4) apply as if the references to D1 were to the most recent determination and the references to D2 were to the new further determination.

Determinations of reserved locations: supplemental matters

43.—(1) Once the NHSCB has determined whether or not an area is a reserved location under regulation 41(2) or 42(1), it must—

(a) give notice of the determination to the person in relation to whose pharmacy premises or proposed pharmacy premises the determination relates, and to the persons notified in accordance with regulation 41(4) or 42(2); and

(b) as part of that notice, inform them of—

(i) its determination and the reasons for it, and

(ii) in the case of any person notified who is a Local Pharmaceutical Committee, a Local Medical Committee, a provider of primary medical services, an LPS chemist or a person on a pharmaceutical or dispensing doctors list, their right of appeal under regulation 45(1)(c) or (d).

(2) Where—

(a) part of the area of what would otherwise be determined under regulation 41(2) or 42(1) to be a reserved location is within 1.6 kilometres of the location of other pharmacy premises (that is, pharmacy premises other than the pharmacy premises at the relevant location); and

(b) there is no reserved location arising out of the presence of those other pharmacy premises,

that part of that area is not to be part of the reserved location.

(3) A reserved location (as opposed to the determination of a reserved location) takes effect once the pharmacy premises to which it relates are listed in the pharmaceutical list.

(4) Once a reserved location takes effect, the NHSCB must—

(a) delineate precisely the boundary of the reserved location on a map;

(b) publish that map; and

(c) make that map available as soon as is practicable to any HWB that has all or part of that reserved location in its area.

Prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location

44.—(1) This paragraph applies to all routine applications—

(a) for inclusion in a pharmaceutical list as an NHS pharmacist; or

(b) from an NHS pharmacist included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, additional pharmacy premises from which to provide pharmaceutical services.

(2) As regards any application to which paragraph (1) applies, the NHSCB must have regard to whether or not the applicant is seeking the listing of pharmacy premises which are in a part of a controlled locality that is not a reserved location.

(3) If the applicant is seeking the listing of pharmacy premises which are in a part of a controlled locality that is not in a reserved location, the NHSCB must refuse the application if granting it would, in the opinion of the NHSCB, prejudice the proper provision of relevant NHS services in the area of—

(a) the relevant HWB; or

(b) a neighbouring HWB of the relevant HWB.

(4) For the purposes of paragraphs (2) and (3), if no particular premises are proposed for listing in the application, the applicant is to be treated as seeking the listing of pharmacy premises which are in a controlled locality if the best estimate that the NHSCB is able to make of where the proposed pharmacy premises would be is at a location which is in a controlled locality, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

Appeals against decisions under Part 7

45.—(1) A person with appeal rights (as provided for in this regulation) may appeal to the Secretary of State against the following decisions by the NHSCB—

(a) a determination of whether or not an area is or is part of a controlled locality as mentioned in regulation 36(2), in respect of which the only people with appeal rights are—

(i) a person, as mentioned in regulation 38(4), who is making a routine application to which the determination relates, and

(ii) a person given notice of the determination who is mentioned in regulation 39(2)(b)(iii);

(b) a decision under regulation 37(3) that an application by a Local Pharmaceutical Committee or Local Medical Committee raises a question that it cannot consider by virtue of regulation 36(3), in respect of which only the Committee making the application to which the decision relates is a person with appeal rights;

(c) a determination as to whether or not a relevant location is in a reserved location under regulation 41(2), in respect of which the only people with appeal rights are—

(i) the person making the application to which the determination relates, and

(ii) a person given notice of the determination who is mentioned in regulation 43(1)(b)(ii); and

(d) a determination under regulation 42(1), in respect of which the only people with appeal rights are—

(i) the person making the application to which the determination relates, and

(ii) a person given notice of the determination who is mentioned in regulation 43(1)(b)(ii),

provided that, within 30 days of the date on which they were notified of the decision that is being appealed, they notify the Secretary of State with a valid notice of appeal.

(2) A notice of appeal under paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

(3) Schedule 3 has effect in relation to appeals to the Secretary of State against decisions under this Part (as it does in relation to appeals against decisions under Parts 2 to 5, 8, 10 and 12 and Schedule 2).

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

– blanket amendment words substituted by S.I. 2023/1071 Sch. para. 1